Blood-Stream Infection (CDC)

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Sent: Monday, November 30, 2009 4:06 PM

To: Blood-Stream Infection (CDC)

Subject: Comments on the Draft Guideline for the Prevention of Intravascular Catheter-Related Infections

The following comments are offered by the faculty of the National Association of Children's Hospitals and Related Institutions (NACHRI) Pediatric Intensive Care Unit (PICU) Central Venous Catheter Associated Bloodstream Infection (CA-BSI) Improvement Collaborative. Faculty members include: Marlene R. Miller, M.D., M.Sc., Department of Pediatrics, The Johns Hopkins University School of Medicine, Baltimore, MD; Richard J. Brilli, M.D., Department of Pediatrics, Nationwide Children's Hospital, Columbus, OH; W. Charles Huskins, M.D., M.Sc., College of Medicine, Mayo Clinic, Rochester, MN; Deborah Campbell, R.N.C., M.S.N., C.C.R.N., Kosair Children's Hospital, Louisville, KY; Debra Ridling, R.N., M.S., C.C.R.N., Children's Hospital and Regional Medical Center, Seattle, WA; Michelle Moss, M.D., Arkansas Children's Hospital, Little Rock, AK; Matthew Niedner, M.D., Children's Hospital of Michigan, Ann Arbor, MI; Thomas B. Rice, M.D., Children's Hospital of Wisconsin, Milwaukee, WI; Steven Muething, M.D., Center for Child Health Quality, Divisions of Health Policy and Clinical Effectiveness and General Pediatrics, Cincinnati Children's Hospital, Cincinnati, OH.

We thank the members of the writing committee for their thorough review of the literature, careful deliberation and clear articulation of important recommendations to prevent catheter-related infections.

As background for our comments, the NACHRI PICU CA-BSI Collaborative is a quality improvement initiative that currently includes 69 PICUs in 59 institutions. The initiative has included 3 phases: Phase 1 (launched in 2006 involving 29 PICUs); Phase II (launched in 2008 involving 25 additional PICUs); Phase III (launched in 2009 involving 15 additional PICUs). The collaborative's objective is to eliminate CA-BSI by optimizing implementation of a pediatric central venous catheter insertion bundle and by developing, evaluating, and optimizing implementation of a pediatric maintenance bundle. The insertion bundle is based primarily on recommendations contained in the 2002 *Guideline for Prevention of Intravascular Device-Related Infections*. The maintenance bundle is also based on 2002 guideline but our bundle addresses areas of maintenance care not addressed in this guideline.

The insertion bundle includes the following practices: hand washing before the procedure; chlorhexidine scrub at insertion site for all children ≥ 2 months (and optionally for younger children); no use of iodine ointment at the insertion site; use of a prepackaged or filled insertion cart, tray, or box with maximal sterile barrier precautions as designated by each institution; use of an insertion checklist with empowerment of observers to stop a non-emergent procedure if sterile insertion practices were not followed; use of polyurethane or Teflon catheters only; completion of insertion procedure training for all providers. This pediatric insertion bundle does not discourage femoral central lines for children as the association between use of a femoral line and CA-BSI is not clear for children, unlike the data for adult patients.

The maintenance bundle includes the following practices: daily assessment of the need for the catheter with prompt removal if the catheter was no longer needed; daily assessment of the catheter insertion site for evidence of infection; catheter insertion site care including no use of iodine ointment, a chlorhexidine scrub of the insertion site with dressing changes; dressing changes if the dressing was soiled, dampened, or loosened otherwise every 2 days for gauze dressings and every 7 days for

transparent dressings, and use of prepackaged dressing change kits; and catheter hub/cap/tubing care including changes of administration sets, including add on devices, no more frequently than every 72 hours (unless soiled or suspected to be infected), replacement of tubing used to administer blood, blood products, or lipids within 24 hours of initiating infusion, and replacement of caps no more often than 72 hours (or per manufacturers recommendations) or when administration set were changed; use of a prepackaged cap change kit, cart, or central location as designated by each institution.

The initial results of the Collaborative are described in a forthcoming publication (Miller MR, et al. Pediatrics, in press for February 2010). During the first year of Phase I, the incidence of pediatric CA-BSI was reduced by 43% (5.4 vs 3.1 CA-BSIs/1,000 central line days; $p < 0.0001$). Using hierarchical cluster analysis regression modeling with adjustment for geographic region and PICU demographics (average length of stay and bed capacity), we found that the only factor associated with the observed decrease in the incidence of BSI was adherence with the insertion and maintenance bundles collectively (Relative Rate 0.57, 95% Confidence Interval 0.45 – 0.74, $p<0.0001$). Using this modeling approach to assess relative importance of the insertion versus the maintenance bundles, we found that adherence with the pediatric maintenance bundle was the only factor associated with the decrease in the incidence of pediatric CA-BSI (Relative Rate 0.41, 95% Confidence Interval 0.20 – 0.85, $p = 0.017$).

Additionally, we observed that the incidence of CA-BSI decreased with compliance with maintenance practices approaching 90-95%. To date our Phase I PICUs have been working to sustain the reliable implementation of our pediatric bundles for over 3 years. The most current aggregate CA-BSI rate among these 29 PICUs is 1.8 CA-BSI/1,000 central line days for 9 month period from January - September 2009.

The following are our specific comments.

Introduction
(Page 2-3, lines 56-66) Based on the results described above, the guideline should also emphasize key maintenance practices. The recommendations should be as specific as possible (see comments below), noting areas where evidence is inadequate. The guideline should also include a recommendation to use hospital-specific or collaborative-based performance improvement initiatives to improve performance regarding maintenance practices, including measurement of compliance with maintenance care practices (see below).

Epidemiology and microbiology in adult and pediatric patients
(Page 8, lines 177-82; Page 9, 197-205) The discussion of CA-BSI rates in pediatric patients across these two pages is disjointed. We suggest the discussion be updated and consolidated to one paragraph highlighting differences in CA-BSI rates in PICUs vs. adult ICUs and the stratification of C A-BSIs in NICUs by birthweight and the use of central lines vs. umbilical lines.

Education, training and staffing
(Recommendation 3; page 11, line 265-6) The specific elements of competency should be defined. Based on the strong evidence of our experience with 29 PICUs during Phase I, we suggest that competency with respect to the central line maintenance should be demonstrated for hand hygiene, dressing changes, administration set (tubing) and cap changes, and disinfection of the cap before central line entry.

Hand hygiene and aseptic technique
(Recommendation 4 [note that 2 recommendations are labeled with the number 4]; page 17, line 387-8) This recommendation should be made more specific. For what purpose should gloves be worn: to

prevent a catheter associated infection; to prevent exposure of healthcare workers to bloodborne pathogens; or both? Given the designation of the evidence as Category 1C, it appears the intent is to prevent exposure of healthcare workers to bloodborne pathogens. In addition, should there be any difference in the use of clean vs. sterile glove by the type of catheter? Our group has reached consensus to require use of sterile gloves during central line dressing changes.

In addition, no recommendation is made regarding use of gloves when accessing the central line or the attached infusion set (i.e., should they be worn or not, clean vs. sterile gloves). Our group has reached consensus to require hand hygiene and use of clean gloves before entering a central line to prevent contamination of the catheter/hub/cap.

Catheter site dressing regimens
(Recommendations 6 and 7; page 21, lines 472-7) Viewed together, these two recommendations indicate that the frequency of dressing change should be distinctly different for short term central lines vs. tunneled or implanted central lines. Recommendation 6 states that transparent dressings for short term central lines should be changed "at least every 7 days" (implying that dressings could also be changed more frequently). Recommendation 7 states that dressings for tunneled or implanted central lines should be changed "no more than once per week." The same study (reference 149) is cited as evidence for both recommendations. Unless there is evidence supporting this distinction, we believe that reliable implementation will be enhanced by reconciling and simplifying these recommendations. We suggest that transparent dressings for all central lines be changed every 7 days, unless otherwise indicated.

(Recommendation 11; page 21, lines 483-6) Although not yet in press, during our three plus years of PICU CA-BSI effort we incorporated an 18 month factorial design trial of chlorhexidine impregnated sponges to assess their impact on the incidence of CA-BSI in PICU patients in the context of reliable implementation of baseline pediatric insertion and maintenance bundles. The data showed no significant difference in CA-BSI rates with the addition of chlorhexidine impregnated sponges. Given the added costs of sponges, potential complications such as inadvertent line dislodgement/removal during sponge removal, we believe the evidence is insufficient to recommend routine use of chlorhexidine impregnated sponges in children.

Patient cleansing
(Recommendation; page 24, lines 539) We are aware of several studies ongoing to evaluate the efficacy and safety of chlorhexidine bathing for children and infants. Although we recognize data from these studies is forthcoming, we believe the current data is insufficient to recommend routine use of chlorhexidine bathing in children.

Catheter securement devices
(Recommendation; page 24, lines 549) We are not aware of any data in pediatrics to suggest that sutureless securement devices are effective or safe. Given the challenges in children to secure all devices, including PICC lines, we believe this recommendation should be confined to adults and the language should state. "In adult patients, use a sutureless securement device..."

Peripheral arterial catheters and pressure monitoring devices for adult and pediatric patients
(Recommendation 11; page 45, lines 1009-12) The recommendation to minimize the number of manipulations and entries into the pressure monitoring system is very important. However, this is an important prevention intervention for all types of intravascular catheters. This recommendation should be generalized to all intravascular catheters and included in the "needleless intravascular catheter systems" section.

Replacement of administration sets
(Recommendation 1; page 46, lines 1044-6) Because administration sets will likely be changed (some would say should be changed) at the same time as the needleless intravascular catheter systems, these recommendations should be reconciled with the recommendation regarding replacement of these systems (see below, Recommendation 1 and 2, page 47, lines 1066-71). As previously noted regarding the frequency of dressing changes, we believe that reliable implementation will be enhanced by reconciling and simplifying these recommendations. We believe a recommendation of change every 72-96 hours would be reasonable.

Needleless intravascular catheter systems
(Recommendations 1 and 2; page 47, lines 1066-71) Because these devices will likely be changed (some would say should be changed) at the same time as the administration sets, these recommendations should be reconciled with the recommendation regarding replacement of administration sets (Recommendation 1, page 46, lines 1044-6). As previously noted regarding the frequency of dressing changes, we believe that reliable implementation will be enhanced by reconciling and simplifying these recommendations. We believe a recommendation of change every 72-96 hours would be reasonable.

(Recommendation 4; page 48, lines 1075-6) It is unclear why chlorhexidine is preferred. If alcohol (70%) is regarded as adequate for cleansing the diaphragm of multidose vials (Recommendation 6, page 51, lines 1144-5), it is unclear why this is not an acceptable alternative for cleansing the access port (cap). Merely "wiping the access port" is not likely to be sufficient for disinfection regardless of whether chlorhexidine or alcohol is used. We suggest that the recommendation state that the port (cap) should be scrubbed with either alcohol or chlorhexidine for a specified duration (i.e., 15 seconds) (Kaler W, Chinn R. Journal of the Association for Vascular Access 2007; 12: 140-2). The concentration of alcohol and chlorhexidine should also be specified.

Multidose parenteral medication vials and parenteral fluids
(Recommendation 12; page 51, lines 1155-7) We suggest a single recommendation regarding the time period during which the infusion of lipids should be completed (i.e., either 12 hours or 24 hours).

Performance improvement
(Recommendation; page 52, lines 1075-77) The results of the NACHRI PICU CA-BSI Collaborative represent additional evidence of the effectiveness of a collaborative-based improvement initiative in reducing the incidence of CA-BSI (Miller M, et al. Pediatrics 2010, in press). These results also provide evidence that a bundle of evidence-based maintenance practices is effective in reducing the incidence of CA-BSI.

Additional comments

We suggest that the guideline make recommendations regarding the insertion and maintenance of extracorporeal membrane oxygenation (ECMO) catheters.

We suggest that the guideline include recommendations regarding implanted ports, such as the procedure for needle access of the port, frequency of dressing and needle change, etc.

We suggest that two types of central line entry be distinguished:

> 1) Central line entries that involve disconnecting the administration set from the catheter or disconnecting portions of the administration set from each other (i.e., entries that expose interior surfaces of the catheter cap or the administration);

2) Central line entries that involve entering the catheter or administration set through a closed port or cap.

Because of the risk associated with contamination of the interior surface of the catheter cap or administration set, we believe the first type of central line entry should be treated like a sterile procedure and requires hand hygiene, use of sterile gloves, use of a mask, and maintenance of a sterile field under the disconnection site.